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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,930	11/30/2001	Jane Hirsh	CP 104	2912

23579 7590 07/15/2004

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EXAMINER	
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ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/15/2004

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/015,930
Filing Date: November 30, 2001
Appellants: HIRSH ET AL.

Patrea L. Pabst
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 04/28/04.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on 12/17/03 has not been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-23 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

6,294,199 B1	Conley et al.	09-2001

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conley et al. US 6,294,199.

Conley teaches method of treating a bacterial infection comprising administering composition comprises amoxycillin (see abstract). The composition can be a modified release dosage formulation comprises an immediate release phase and a slow release phase (column 9, lines 5-58). The modified release dosage form can be a dispersible tablet, a swallow tablet, a chewable tablet that may also be effervescent, a capsule or a sachet (column 9, lines 66 through column 10, lines 1-3). The modified release tablet can be formulated in a bi-layered tablet comprises an immediate release layer which comprises amoxycillin, disintegrants, compression aids, diluents, lubricants, and the like, which will disintegrate rapidly; and a slow release layer which comprises

amoxycillin together with release retarding polymers (columns 11-12). Columns 15-17 disclose the process of making the composition.

Conley is silent as to the teaching that the immediate release layer dissolved intraorally. However, Conley teaches the modified release formulation that can be formulated in a chewable tablet. Thus, such language does suggest the active agent in the immediate release layer disintegrates rapidly in the mouth, and therefore, provide intraoral absorption. Accordingly, it would have been *prima facie* obvious for one of ordinary skill in this art to optimize Conley's modified release formulation with the expectation of at least similar result, because Conley teaches the advantageous result in the use of bi-layer chewable/effervescent tablet comprising active agent in both, the immediate release layer, and the delay/slow release layer.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Conley et al.

Conley is relied upon for the reason stated above. The reference is silent as to the method of administering the modified release formulation as claimed in claim 21. However, Conley teaches a bi-layer chewable tablet that comprises an immediate release layer that will disintegrate rapidly; and a slow release layer which after oral ingestion will disintegrate/dissolve in the intestine (columns 11-12). Thus, it is the position of the examiner that such language does suggests that after the effervescent of the immediate release layer in the mouth, the ingestion of the slow release layer then occurs. Therefore, it would have been *prima facie* obvious for one of ordinary skill in the

art to, by routine experimentation determine a suitable administration method with the expectation of at least similar result, because Conley teaches a modify release formulation having biphasic release profile that fall within the claimed range (column 9, lines 28-44).

(11) Response to Argument

Appellants argue that the amoxycillin taught by Conley is not a suitable for intraoral administration since it molecular weight is above 350 and is only slightly soluble in water and therefore not rapidly released. Contrary to the appellants' argument, the rejected claims do not require that the active agent be a water-soluble and has a molecular weight below 350. It is well known in pharmaceutical art that amoxycillin is suitable for intra-oral dosage form. To be more significant, Athanikar (is cited merely as a teaching reference) for the teachings of a per-oral composition comprising amoxycillin in the form of polymer film adhesive to allow amoxycillin to adhere to the oral mucosa (column 3, lines 48-62 and column 6, lines 1-22). Conley teaches the dosage form containing amoxycillin in a chewable form. Accordingly, amoxycillin is a candidate for intra-oral administration.

Appellant argues that Conley does not describe an immediate release layer that dissolves intraorally to release amoxycillin for intraoral absorption. However, it is noted that the limitations "capable of intraoral administration" and "capable of oral administration" recited in the independent claims are merely states, for example, as an intended use of the invention. The intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in

the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the preamble is not considered a limitation and is of no significance to claim construction. Nonetheless, applicant's attention is called to column 7, lines 8-15, Conley teaches an immediate release chewable or dispersible tablets that dissolves essentially completely within 30 minutes (column 9, lines 39-40). Thus, it would have been obvious for one of ordinary skill in the art to chew the chewable tablet (not swallowing it) in a substantial amount of time to inhibit the absorption of the active agent through the oral mucosa, because Conley teaches the immediate release layer that disintegrates immediately or rapidly in contact with water or aqueous media (column 11, lines 45-65).

Appellants argue that the active ingredients of appellants' claimed composition and method are systemically active agents that are absorbed into the bloodstream at two different sites of the human body. In response to appellants' argument, it is noted that the features upon which applicant relies (i.e., active ingredients that are systemically active agents and absorbed into the bloodstream) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Appellants argue that Conley does not teach the method of claim 21, which requires the tablet be kept in the mouth until the intraoral portion is dissolved. Appellants further alleged that it is essential to dissolve the intraoral portion in the

mouth, or the does of the drug intended for intraoral administration will not enter systemic circulation via transmucosal absorption in the oral cavity. However, it is the position of the examiner that the properties desired by the appellants are inherent, because Conley teaches a chewable tablet having an immediate release composition that disintegrate immediately or rapidly in contact with aqueous media. Products of identical chemical composition cannot have mutually exclusive properties. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The inherent teaching of a prior art reference arises both in the context of anticipation and obviousness. *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

S. Tran
July 2, 2004

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